ISRCTN19301859 https://doi.org/10.1186/ISRCTN19301859

The beneficial effect of a food supplement based on arabinoxylans obtained from barley on blood sugar levels after eating

Submission date
22/02/2022

Recruitment status
No longer recruiting

Registration date
22/03/2022

Overall study status
Completed

Last Edited
18/10/2022

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Several cereals, including barley, contain a soluble fiber in which arabinoxylans (AX) are present. AX have attracted the interest of the medical-scientific community for beneficial activities such as:
1. Increased food bolus (mass of chewed food) viscosity, which reduces sugar and cholesterol absorption
2. Reduction in gastric (stomach) emptying time and increased satiety (fullness)
3. A beneficial effect on the intestinal mucosa (lining), due to the breakdown of these compounds by microorganisms, which releases short-chain fatty acids into the intestines
The aim of this study is to demonstrate that arabinoxylans obtained from barley reduce blood sugar after meals in healthy volunteers.

Who can participate?
Healthy volunteers aged between 18 and 65 years

What does the study involve?
Participants are randomly allocated into two groups to take a food supplement containing AX obtained from barley or a placebo (dummy supplement). After a 5-day wash-out period (in which participants take no supplements), the groups swap to the other supplement. Blood sugar and insulin response are measured at the start of the study, after intake of the supplement and after the wash-out period.

What are the possible benefits and risks of participating?
Participants may benefit from improved blood sugar and insulin response. No adverse events are expected.

Where is the study run from?
Comegen (Italy)

When is the study starting and how long is it expected to run for?
January 2021 to February 2022

Who is funding the study?
HEALLO s.r.l. (Italy)

Who is the main contact?
1. Prof. Maria Daglia (scientific), maria.daglia@unina.it
2. Dr. Alessandra Baldi (public), alessandra.baldi.alimenti@gmail.com

Contact information

Type(s)
Scientific

Contact name
Prof Maria Daglia

ORCID ID
https://orcid.org/0000-0002-4870-7713

Contact details
Università degli Studi di Napoli Federico II
Domenico Montesano street, 49
Naples
Italy
80131
+39 (0)3331703492
maria.daglia@unina.it

Type(s)
Public

Contact name
Dr Alessandra Baldi

Contact details
Università degli Studi di Napoli Federico II
Domenico Montesano street, 49
Naples
Italy
80131
+39 (0)3483854114
alessandra.baldi.alimenti@gmail.com

Additional identifiers

Protocol serial number
AX01

Study information

Scientific Title
Efficacy study of a food supplement based on arabinoxylans obtained from barley on the reduction of postprandial glycemic response in healthy subjects: a monocentric, randomized, cross-over, double-blind, placebo-controlled clinical trial

Acronym
AX

Study objectives
The aim of this study was to demonstrate that arabinoxylans obtained from barley are able to reduce post-prandial blood glucose in healthy subjects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/04/2021, the Ethics Committee of ASL Napoli 1 CENTRO (Via Comunale del Principe, 13/A, 80145, Napoli, Italy; +39 (0)812544495; comitatoetico@aslnapoli1centro.it), ref: Prot n° 222

Primary study design
Interventional

Study design
Interventional monocentric randomized cross-over double-blind placebo-controlled clinical trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Postprandial glycaemic responses

Interventions
The subjects recruited in the present clinical study consume a bakery product (breadsticks) characterized by a high content of available carbohydrates (76.5% of available carbohydrates). In addition to the bakery products, in one case, the subjects consume a soluble granulate in a stick-pack containing the bioactive compound to be dissolved in a glass of water (STANDARD MEAL + arabinoxylans - AX obtained from barley), and in the other case, a soluble granulate in stick-pack containing microcrystalline cellulose to be dissolved in a glass of water (STD MEAL + placebo). Specifically, first the subject consumes the food supplement containing arabinoxylans or microcrystalline cellulose and immediately thereafter the subject consumes a bakery product with plenty of water (500 ml).

The randomization sequence is generated by a statistician using STATA 16 software (Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC) and the randomization list is kept hidden. The participants are assigned to each of the two treatment groups (STD MEAL + AX

and STD MEAL + placebo) casually and by simple randomisation (1:1 allocation ratio). The randomization code will consist of a three-digit number as indicated in the respective Case Report Form (CRF).

In the clinical study, 40 participants were enrolled and divided into two groups (20 for each group):
Group 1: food supplement containing AX obtained from barley and then, after wash-out placebo
Group 2: placebo and then after wash-out a food supplement containing AX obtained from barley

Participants attend two visits (baseline = t0 and after a 5-day wash-out period = t6) in an outpatient setting. After each clinical visit, all data are filled in the case report form (CRF) by physicians. The clinical trial design is reported below:

Baseline visit (t0):
1. Initially subjects underwent a fasting blood draw
2. Subsequently subjects consumed the STD MEAL + AX or the STD MEAL + placebo
3. 15 minutes after ingestion of the bakery product, subjects underwent blood samples to measure glycemia and insulinemia at 15, 30, 60, 90, and 120 minutes after the intake of the treatment and breadsticks

This step was followed by a 5-day wash-out period (in which subjects took no treatment), prior to cross-over of treatments. After the 5-day wash-out period (t6) each subject in the two groups underwent blood sampling again (at the times indicated for t0) for measurement of fasting blood glucose and insulin, subsequently, after ingestion of STD MEAL+ placebo or STD MEAL + AX (according to a cross-over design).

Therefore, the data acquired are information on the sociodemographic, clinical and symptomatologic characteristics of the participants (at t0), glycemia and insulinemia (at t0 and t6).

Intervention Type
Supplement

Primary outcome(s)
Postprandial blood glucose evaluated using blood tests following blood sampling at t0 (on an empty stomach and at 15, 30, 60, 90, and 120 minutes after intake of the treatment and breadsticks) and after 5 days of the wash-out period (in which subjects took no treatment), prior to cross-over of treatments (at the times indicated for t0)

Key secondary outcome(s)
Postprandial insulinemic response evaluated using blood tests following blood sampling at t0 (on an empty stomach and at 15, 30, 60, 90, and 120 minutes after intake of the treatment and breadsticks) and after 5 days of the wash-out period (in which subjects take no treatment), prior to cross-over of treatments (at the times indicated for t0)

Completion date
05/02/2022

Eligibility

Key inclusion criteria
1. Healthy subjects, according to what was determined by the clinical history and by the information provided during the recruitment
2. Aged between 18 and 65 years
3. Non-smokers
4. Subjects able to understand and to sign the Informed Consent

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
40

Key exclusion criteria
1. Subjects with type 1 or 2 diabetes
2. Subjects with fasting blood glucose >110 mg/dl
3. Subjects with blood pressure values >160/100 mmHg
4. Subjects with metabolic disorders
5. Subjects with endocrine, cardiovascular, pulmonary, renal or gastrointestinal diseases, which may interfere with the results of the study
6. Subjects with sensitivity, intolerance or allergy to products used in the clinical trial
7. Pregnant or lactating women
8. Subjects who have donated blood in the 3 months prior to recruitment
9. Subjects under pharmacological treatment, with drugs that could interfere with the study, such as alpha-glucosidase inhibitors (acarbose etc), insulin-sensitive drugs (metformin etc), sulfanilureee, cholesterol medications, and any other medications that the physician does not deem compatible with the study
10. Subjects who were taking food supplements that could interfere with the study, such as products high in vitamins and minerals (>200% VNR), B vitamins, C vitamin, calcium, zinc, copper, chromium, iodine, iron, magnesium, manganese, phosphorus, essential fatty acid products, botanicals, and any other products that the physician does not deem compatible with the study.

Date of first enrolment
09/09/2021

Date of final enrolment
03/12/2021

Locations

Countries of recruitment
Italy

Study participating centre
Comegen
Viale Maria Bakunin 41
Naples
Italy
80126

Sponsor information

Organisation
HEALLO s.r.l.

Funder(s)

Funder type
Industry

Funder Name
HEALLO s.r.l.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/09/2022	18/10/2022	Yes	No